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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/512,926
Filing Date: February 25, 2000
Appellant(s): LAMB, FRED S.

Ann S. Viksnins
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 6, 2005 appealing from the Office action mailed November 30, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

Claim 6 contain(s) substantial errors as presented in the Appendix to the brief. Accordingly, claim 6 is correctly written in the Appendix to the Examiner's Answer.

(8) Evidence Relied Upon

6,197,789 B1 GRAINGER et al. 3-2001

5,470,883 STROMBERG 11-1995

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 6-11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grainger et al. (U.S.Patent No. 6,197,789 B1) of record.

Grainger et al. teach tamoxifen is useful to prevent or treat conditions characterized by **inappropriate or pathological activity of endothelial cells**. (column 6, lines 5-10). Grainger et al. teach tamoxifen **inhibits vascular smooth muscle cells contraction**. (column 17, lines 35-47). Grainger et al. teach tamoxifen is useful on vascular smooth muscle cells to inhibit the pathological activity of the smooth muscle cells, and to inhibit the activation of **endothelial cells associated with vascular surgery, diabetes, hypertension, and coronary artery blockage**. (abstract, column 4, lines 7-16, column 5, line 65 through column 6, line 30, column 7, lines 15-33, column 8, lines 11-20, column 10, lines 51-57, column 15, line 54, column 18, lines 34-44, column 24, lines 47-50, and column 25, lines 4-8). Grainger et al. teach the procedural vascular traumas including **surgical procedures** include vascular surgery (e.g. **angioplasty, coronary bypass) and the pathologies (atherosclerosis, myocardial infraction and stroke**) can be prevented by the administration of tamoxifen. (column 3, lines 30-51, column 4, line 8-25).

Grainger et al. do not expressly teach the normalization of contractile response set forth in claim 1.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Grainger et al. and employ tamoxifen to normalize the contractile response of vasculature in Grainger et al. patients since the teaching of "inhibiting contraction" encompasses the "normalization" since the effect of inhibiting contraction encompasses the "normalization" since the effect of inhibition of the contraction of vascular smooth muscle would "normalize" the contraction of the patients disclosed by Grainger et al.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grainger et al. (U.S.Patent No. 6,197,789 B1) as applied to claims 1, 6-11 and 23 above and further in view of Stromberg (U.S. Patent No. 5,470,883).

Grainger et al. as applied as before.

Grainger et al. do not teach norepinephrine causing the contractile response of vasculature set forth in claim 25.

Stromberg teaches a method of **inhibiting or reversing** the peripheral vasoconstrictive effect of **norepinephrine** set forth in Applicants claim 25 by the oral administration of tamoxifen citrate. (column 2, lines 1-5). Stromberg teaches a method of **blocking or reversing vasoconstriction**, including peripheral vasoconstrictive effects of an intentionally or an unintentionally administered adrenergic agent such as norepinephrine to a subject who receives an injection of such adrenergic agent in a peripheral vascular area is administered a pharmacologically acceptable dose of

tamoxifen citrate to inhibit or reverse the peripheral vasoconstrictive effect of the adrenergic agent (i.e. norepinephrine). (column 2, lines 6-16).

It would have been obvious to one of ordinary skill in the art to employ tamoxifen to normalize the contractile response of vasculature comprising a vascular smooth muscle cell layer and a compromised endothelial cell layer caused by norepinephrine because Stromberg teaches tamoxifen is useful for reversing (normalizing) the vasoconstrictive effect of norepinephrine and because Grainger et al. teach that tamoxifen is useful for inappropriate or pathological activity of vascular smooth muscle cells and endothelial cells. One would have been motivated to employ tamoxifen to reverse (normalize) the contractile response of norepinephrine to achieve inhibition of contraction of vasculature caused by norepinephrine and to treat inappropriate or pathological activity of vascular smooth muscle cells or endothelial cells as taught by Grainger et al.

(10) Response to Argument

Appellant's argument regarding claims 1, 6-11 and 23 unpatentable over the Grainger et al. patent that the Grainger et al. patent does not teach or suggest using tamoxifen to normalize the contractile response of vasculature having a vascular smooth muscle cell (VSMC) layer and a compromised endothelial cell layer is not persuasive because Grainger et al. teach that tamoxifen is useful to prevent or treat conditions characterized by inappropriate or pathological activity of endothelial cells (column 6, lines 5-10) and that tamoxifen **inhibits** vascular smooth muscle cells

contraction. (column 17, lines 35-47). Therefore, it would have been obvious to one of ordinary skill in the art to modify the teaching of Grainger et al. and employ tamoxifen to normalize the contractile response of vasculature because the teaching of "inhibiting contraction" encompasses the "normalization". It is the Examiner's position that by inhibiting contraction, normalcy of VSMC is maintained. Appellant argues that inhibition of VSMC contraction is not equivalent to normalization of smooth muscle cells and that the Merriam-Webster online dictionary defines the term "normalize' as "reduce to a norm or standard" and the Figures 2 and 3 of Appellant's specification clearly depict the normalization response by showing that the contractile response of compromised VSMC treated with tamoxifen was essentially the same as the contractile response of intact VSM. This is not persuasive because Appellant's Figures 2 and 3 have been carefully considered but it deemed to show that the tamoxifen treated compromised VSMC cause to maintain within its "normalcy" by inhibiting the contraction. Therefore, the Grainger et al's teaching of "inhibition of contraction" of VSMC by tamoxifen maintains VSMC's to its norm.

Appellant argues neither the Grainger et al. patent nor the Stromberg patent suggests using tamoxifen to normalize contraction. This is not persuasive that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed.

Cir. 1992). In this case, because Stromberg teaches tamoxifen is useful for reversing (normalizing) the vasoconstrictive effect of norepinephrine and because Grainger et al. teach that tamoxifen is useful for inhibiting contraction of VSMC to treat inappropriate or pathological activity of vascular smooth muscle cells, it would have been obvious to one of ordinary skill in the art to employ tamoxifen to inhibit the contraction of VSMC to maintain its "normalcy" caused by a vasoconstrictive agent including norepinephrine in order maintain it's normalcy by inhibition of contraction including vasoconstriction effect of norepinephrine.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) Appendix

6. A method of claim 23, wherein the compound administered is 1-p-β-dimethylaminoethoxyphenyl-trans-1,2-diphenylbut-1-ene, or a pharmaceutically acceptable salt thereof.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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